



State of West Virginia *Board of Medicine*

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PRESIDENT

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ASHISH P. SHETH, MD
VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 25, 2019

SUMMARY OF COMMENTS RECEIVED REGARDING PROPOSED AMENDMENTS TO 11 CSR 1B AND RESPONSES OF THE WEST VIRGINIA BOARD OF MEDICINE

On June 19, 2019, the West Virginia Board of Medicine filed a Notice of Comment Period on a Proposed Rule, 11 CSR 1B. The Notice established a thirty day comment period on the proposed rule, which concluded at 4:30 pm on July 19, 2019. During the comment period, the Board received seven comments.¹ The Board has reviewed all comments received, and on July 23, 2019, the following responses were authorized by the Board. A copy of this summary is being provided to each commenter. The Board extends its sincere appreciation and gratitude to all individuals and groups who took the time to review and comment upon the proposed amendments to 11 CSR 1B.

Commenter	Date Received
1. Dr. Mittal	June 19, 2019

Dr. Mittal commented in opposition to proposed amendments to subsections 8.1 and 8.2 of 11 CSR 1B. Dr. Mittal commented that physician supervision of PAs is "misconstrued as an effort by physicians, to control other forms of providers, in clinical settings. But contrary, to the fact, it is in regards to the level of training one requires to care for another human being." Dr. Mittal suggests that reducing training and education of physicians would be a better way to address physician shortages in rural areas. Dr. Mittal also points out that the proliferation of the use of the honorific "Dr." by non-physician practitioners creates confusion for patients. Dr. Mittal suggests that the number of physician assistants practicing in rural shortage areas versus

¹ Copies of all comments received are on file with the West Virginia Board of Medicine and the West Virginia Secretary of State.

**SUMMARY OF COMMENTS RECEIVED REGARDING
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physicians should be looked at, and that shifting care to less educated professionals is not a meaningful response to resolve physician shortages in rural areas.

Response: The proposed amendments to 11 CSR 1B, including the amendments to subsections 8.1 and 8.2 do not modify current law, which requires physician assistants to practice in collaboration with physicians. Consistent with Senate Bill 668, the proposed amendments to 11 CSR 1B prohibit independent practice by physician assistants and require physician assistants to practice in collaboration with physicians. With regard to the use of the honorific "Dr." 11 CSR 1B requires physician assistants to identify themselves with the professional designation of PA or PA-C in a section of the rule that was renumbered, but not substantively amended. See Section 18.1. Additionally it has been, and continues to be, grounds for disciplinary action if a physician assistant impersonates a licensed physician or to knowingly permit another person to misrepresent the physician assistant as a physician. See Sections 21.1.g and 21.1.i. The Board has not modified the proposed rule amendments as a result of this comment.

Commenter	Date Received
2. Sudha Reddy	June 24, 2019

This individual transmitted an electronic reply to the Board's eblast notifying licensees of the comment period on the proposed amendments to 11 CSR 1B and the Board's newly proposed fee waiver rule, 11 CSR 13. There was no content to the submitted email reply, but the correspondence is included herewith for completeness of the rulemaking record.

Response: The commenter was contacted in response to the email and notified regarding how to review the agency approved rule once it is filed with the Secretary of State's Office. The Board has not modified the proposed rule amendments as a result of this comment.

Commenter	Date Received
3. Cyrus Tahernia, MD Emeritus	July 1, 2019

Dr. Tahernia submitted a comment generally in support of the proposed amendments to 11 CSR 1B. Dr. Tahernia did note one issue regarding continuing education for retired physicians and physician assistants. The Board believes that Dr. Tahernia intended to convey that retired physician assistants and physicians should not need to complete continuing education because they cannot practice in West Virginia.

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Response: The West Virginia Board of Medicine currently has one license status for physician assistants: active. As the Board does not currently offer a retired status license, it has not contemplated whether continuing education should be required in that circumstance. The Board has not modified the proposed rule amendments as a result of this comment.

Commenter

4. West Virginia Hospital Association

Date Received

July 12, 2019

The West Virginia Hospital Association ["WVHA"] submitted a comment on behalf of its 63 member hospitals and health systems. The WVHA specifically commented on the definition of hospital as set forth in the amendments to the proposed rule. Specifically, WVHA comments that the "definition of 'hospital' has been amended in this rule to add additional restrictions not found in the authorizing legislation." The WVHA contends that the changes to the definition conflict with the definition of "hospital" in the authorizing legislation, and recommends "removing the additional language proposed to be added to the definition of 'hospital' to avoid confusion and to maintain consistency between the rule and the statute."

Response: As a result of WVHA's comment, the Board reviewed the definition of hospital included at 2.1.q of the proposed rule amendments:

2.1.q. "Hospital" means a facility licensed as a hospital pursuant to W. Va. Code §16-5B-1 et seq., and any acute-care facility operated by the state government that primarily provides inpatient diagnostic, treatment or rehabilitative services to injured, disabled or sick persons under the supervision of physicians and includes psychiatric hospitals. Hospital does not include any health care facility which provides health care services to persons on an outpatient basis, even if the facility: is physically attached to the hospital; is situated within the physical boundaries of a hospital; or is operated by or in connection with a hospital.

The Board did not intend to change to definition of the term hospital by adding a second clarifying sentence in this rule. Rather, the Board's intention was to provide clarity and additional information and guidance to physician assistants in determining whether their practice setting makes them eligible to file a Practice Notification. While the Board does not believe that its original language meaningfully changed the definition of "hospital," it acknowledges that the reference to outpatient care could be misconstrued. The Board's desire to provide clarification to physician assistants can be better met with a modification to this language which also eliminates any concern that the definition of the term hospital has been altered. The Board's agency

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approved rule, filed contemporaneously with this summary, modifies the language of the second sentence in response to WVHA's helpful comment as follows:

2.1.eq. "Hospital" means a facility licensed as a hospital pursuant to W. Va. Code §16-5B-1 et seq., and any acute-care facility operated by the state government that primarily provides inpatient diagnostic, treatment or rehabilitative services to injured, disabled or sick persons under the supervision of physicians and includes psychiatric hospitals. Hospital does not include any health care facility which is not licensed as a hospital pursuant to W. Va. Code §16-5B-1 et seq., even if the facility: is physically attached to the hospital; is situated within the physical boundaries of a hospital; or is operated by or in connection with a hospital.

Commenter

5. Gary Reed Culver, PA-C, MMS

Date Received

July 16, 2019

Mr. Culver expressed disappointment that Senate Bill 668 "didn't encompass all physician assistants who fall under institutional hospital credentialing, but rather only those who work inpatient." He indicated that some physician assistants are subject to hospital credentialing but are ineligible to practice pursuant to Practice Notifications because they do not practice as part of the inpatient services provided by a hospital. Mr. Culver did note that he perceives Senate Bill 668 to be "a significant step. . . forward" and expressed hope that "it will be followed in the years to come by legislation that will realize and embrace the wisdom of removing the necessity for individual practice agreements." Mr. Culver also describes the history and development of the physician assistant profession and expressed a desire for a future where physician assistants are not "tethered" to a physician, but still practice in collaboration with physicians.

Response: The commenter did not identify any specific recommended change to the proposed rule. His concern appears to be more generally related to the authorizing legislation. As the commenter acknowledged, the proposed amendments are consistent with the changes implemented by Senate Bill 668. Senate Bill 668 limits the use of practice notifications to physician assistants who work in hospitals. The Board has not modified the proposed rule amendments as a result of this comment.

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Commenter

6. Ginger Boles, MS PA-C

Date Received

July 17, 2019

Ms. Boles commented to raise concerns regarding a new definition included in the proposed amendments for the term “prescriptive authority.” The commenter indicated that the new definition “could create confusion for physician assistants who are working in hospitals where treatment and medication orders are written. I do not think it is the intent of these rules, based on recent statutory changes, to make prescriptions and orders one and the same. There has always been a clear distinction that a prescription for a medication is for outpatient delivery, while an order for a medication is for inpatient delivery.” The commenter further indicates that “[t]he DEA confirms this in the following statement which can be found on their website; a prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).”

This commenter opines that, based upon the guidance she has cited, that “medication orders within an institutional setting for immediate delivery have never been nor should they be regulated by a PA formulary intended for prescriptive authority.” Ms. Bowles requests that the Board modify the proposed rules as the Board of Medicine deems necessary “to make sure that all the sections dealing with order or orders does not create confusion or unintentionally limit the well-established practice of physician assistants writing orders within a hospital setting, based upon the protocols, guidelines, and best practices of the institution.”

Response: The proposed rule amendments were not intended to modify current physician assistant practice. They are only intended to implement a new and less burdensome regulatory process for physician assistants practicing in hospitals. The issue raised by Ms. Culver identifies an unintended collateral consequence of the language modifications made to the rule to accommodate parallel, but separate, authorization processes for PAs who work in hospital settings versus non-hospital settings. To ensure that the regulatory changes do not affect physician assistant practice, the Board added the language which appears in bold font to subsection 15.3 of the proposed amended rule:

15.3. On an annual basis, the Board shall approve and publish on its website a list classifying pharmacologic categories of all drugs which are not within a physician assistant's prescriptive authority. This list shall, at a minimum, exclude the following drugs from physician assistant prescriptive authority:

15.3.a. Schedules I and II of the Uniform Controlled Substances Act;

15.3.b. Antineoplastics

15.3.c. Radio-pharmaceuticals; and

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15.3.d. General anesthetics.

The prescriptive authority for physician assistants with respect to medications listed under Schedule III of the Uniform Controlled Substances Act shall be limited to a 30 day supply without refill.

The limitations on physician assistant prescriptive authority set forth in this subsection do not apply to:

Medications administered or dispensed by a physician assistant in a hospital pursuant to physician orders; or

The ordering of medications for hospital patients by a physician assistant who is authorized and/or credentialed by the hospital to issue such orders.

Commenter

Date Received

7. American Academy of Physician Assistants/
West Virginia Association of Physician Assistants

July 19, 2019

The American Academy of Physician Assistants (“AAPA”) filed comments regarding the proposed amendments on behalf of itself and the West Virginia Association of Physician Assistants (“WVAPA”).² This commenter generally raised concerns that the proposed amendments “directly conflict with the intent and perceived goals of the underlying statute[,]” and provided specific comments on certain sections of the proposed rule that are the basis of the generalized concern. Additionally, the commenter identified a typographical/grammatical concern with the modified definition of licensure in subdivision 2.1.t, which the Board agrees needs corrected in the agency-approved version of this rule.

The commenter first raises concerns that subdivisions 9.5.b and 14.4.c., which require physician assistants and hospitals to identify whether or not a physician assistant is authorized to sign death certificates on behalf of a hospital, are included in the Practice Notification requirements. In opposition to this language, the commenter suggests that Senate Bill 668 was intended to permit the scope of practice for PAs providing care in hospitals to be determined at the practice level as approved by the hospital, and that the proposed rule language does not align with this goal. If the Board understands the comment correctly, the commenter is suggesting that authorization for a PA to sign death certificates should not be reportable on the Practice Notification form.

² For ease of reference, these entities are collectively referred to as “the commenter.”

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Second, the commenter notes that Section 15, which governs PA prescriptive authority in a hospital does not contain language which permits a hospital-based physician assistant to accept free samples or to apply to be registered as a controlled substance dispensing practitioner. The commenter suggests that Section 15 should be modified to make it clear that physician assistants who are practicing pursuant to a practice notification have “parallel authority” with physician assistants who do not practice in hospitals.

Response: The Board carefully reviewed and considered these comments, and appreciates the opportunity to address the issues raised therein. With respect to the commenter’s concern regarding subdivisions 9.5.b and 14.4.c, the Board has strived to make Practice Notification forms as streamlined as possible. The form will require physician assistants and hospitals to provide specific details about the physician assistant’s collaborating physicians or the delegated medical acts the hospital credentials the physician assistant to perform. However, physician assistants were recently granted statutory authority to sign death certificates if they have completed appropriate training and are delegated this medical act. On a monthly basis, the Board provides a list of physician assistants who are eligible to complete death certificates to the state’s Vital Registration Office. It is the Board’s understanding that the Vital Registration Office relies on this information to determine whether to accept certain death certificates. Currently, this information is collected on physician assistant Practice Agreements. Pursuant to Senate Bill 668, Practice Notifications will replace Practice Agreements for hospital-based physician assistants. Accordingly, to provide accurate data to the Vital Registration Office, the Board needs to collect information regarding physician assistant authorization to complete death certificates on the Practice Notification. Including this information on the Practice Notification does not alter the fact that the decision regarding whether or not to authorize a physician assistant to complete death certificates is made at the practice level by the hospital and physician assistant. The Board has not made any changes to the proposed amended rule as a result of this comment.

The Board also considered the commenter’s suggestion that section 15 of the proposed amended rule be modified to authorize physician assistants in hospitals to accept free samples and register as controlled substance dispensing practitioners. These provisions appear in section 12 of the proposed amended rule, which governs physician assistant prescriptive authority in non-hospital practice settings. The Board intentionally did not include these provisions in section 15 because they are inapplicable to physician assistant practice in hospitals. Free samples are typically offered to office or clinic-based medical practices for dispensing to outpatients. Additionally, registration as a controlled substance dispensing practitioner is only required for Board licensees who administer or dispense controlled substances in an office-based setting. Pursuant to the Board’s dispensing rule, 11 CSR 5, practitioners who dispense or administer controlled

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substances in a hospital setting are exempt from registration as controlled substance dispensing practitioners.

Finally, the Board has corrected the typographical error that the commenter identified in the definition of licensure in subdivision 2.1.t. The strikethrough which erroneously extended into the last letter of "assistants" on line two of the definition has been removed.

Conclusion

In conclusion, based upon the comments received, the Board's agency approved filing contains 3 modifications as set forth hereinabove. The Board again expresses its appreciation to all who submitted comments. These thoughtful comments assisted the Board to conduct a robust review of its proposed rule and resulted in three modifications which the Board believes improve the rule.

Frame, Jamie C

Subject: FW: Comment Period Underway for Proposed Board of Medicine Rules West Virginia

From: V mitt <v3mittal@gmail.com>

Sent: Wednesday, June 19, 2019 9:54 PM

To: WV BOM <wvbon@wv.gov>

Subject: Re: Comment Period Underway for Proposed Board of Medicine Rules West Virginia

[Dear Mr Spangler,

As a physician, I oppose the suggested changes in Section 8.1 and 8.2, to PAs not needing physician supervision.

It is misconstrued as an effort by physicians, to control other forms of providers, in clinical settings. But contrary, to the fact, it is in regards to the level of training one requires to care for another human being.

If this is the level of education and training experience, we want in getting treatment for ourselves and our families, we need to significantly shorten medical school duration (6 yrs of medical school directly after HS for practising in rural areas) and requirements for practice!
That will reduce professional shortages.

In name of shortage and some other needs, we can not reduce the need for extensive training for any branch of professionals, to care for other human beings.

Professionals are using Dr even if not medical doctor and ask how many patients get confused, that they are seeing a medical doctor! Why these professionals are not putting their degrees of expertise, when they write doctor, before their names?

Also, even after PA school and training or for any professional branch, what percentage of PAs are ending in shortage areas? How different is it, to percentage of physicians, going to underserved areas?

I appreciate the opportunity, to be allowed, to share my thoughts.

Sincerely,
Dr Mittal MD

On Thu, 20 Jun 2019, 02:09 , <wvbon@wv.gov> wrote:

Comment Period Underway for Proposed Board of Medicine Rules

June 19, 2019

11 CSR 18

The West Virginia Board of Medicine is accepting written comments on proposed amendments to 11 CSR 18, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*. The amendments to this rule implement the provisions of Senate Bill 668 with respect to physician assistant practice. The Board is also in the process of promulgating an emergency rule which incorporates the proposed amendments.

The proposed amendments to 11 CSR 18 are available for review and comment.

11 CSR 13

The Board is also accepting written comments on a proposed new rule series, 11 CSR 13, *Waiver of Initial Licensing Fees or Certain Initial Licensure Applicants*. This rule is intended to implement Senate Bill 396, which authorizes waivers of the initial licensing fee for eligible low income and military family licensure applicants.

Proposed rule 11 CSR 13 is available for review and comment.

The Board encourages all interested persons to review the proposed rulemaking and provide comments on the proposed changes. All comments must be received by 4:30 pm on July 19, 2019, and should be submitted to:

Mark A. Spangler, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311
Mark.A.Spangler@wv.gov



State of West Virginia *Board of Medicine*

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ASHISH P. SHETH, MD
VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 25, 2019

VIA ELECTRONIC MAIL ONLY

Vikrant Mittal, MD
v3mittal@gmail.com

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 1B

Dear Dr. Mittal:

Thank you for taking the time to review and comment on the Board's proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*.

The Legislative Committee of the Board met on Tuesday, July 23, 2019, to review and consider all of the comments that were received. Discussion occurred, and the Board approved some modifications to the proposed rule in response to the comments it received. Enclosed please find a summary of the comments received, which addresses each suggested modification proposed in the comments, and the Board's responses.

The agency-approved version of 11 CSR 1B will be filed with the West Virginia Secretary of State's Office this week and will be available for review on their website at <https://apps.sos.wv.gov/adlaw/csr/>.

Thank you again for your participation in the rulemaking process and for your comments.

Sincerely,

Mark A. Spangler

MAS/jcf
Enclosure

Frame, Jamie C

Subject: FW: Comment Period Underway for Proposed Board of Medicine Rules

From: sudha reddy <suvreddy@yahoo.com>

Sent: Monday, June 24, 2019 12:47 PM

To: WV BOM <wvbom@wv.gov>

Subject: Re: Comment Period Underway for Proposed Board of Medicine Rules

Sent from Yahoo Mail on Android

On Sun, Jun 23, 2019 at 3:21 PM, sudha reddy <suvreddy@yahoo.com> wrote:

Sent from Yahoo Mail on Android

On Wed, Jun 19, 2019 at 4:51 PM, wvbom@wv.gov <wvbom@wv.gov> wrote:

Comment Period Underway for Proposed Board of Medicine Rules

June 19, 2019

11 CSR 1B

The West Virginia Board of Medicine is accepting written comments on proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*. The amendments to this rule implement the provisions of Senate Bill 668 with respect to physician assistant practice. The Board is also in the process of promulgating an emergency rule which incorporates the proposed amendments.

The proposed amendments to 11 CSR 1B are available for review and comment.

11 CSR 13

The Board is also accepting written comments on a proposed new rule series, 11 CSR 13, *Waiver of Initial Licensing Fees or Certain Initial Licensure Applicants*. This rule is intended to implement Senate Bill 396, which authorizes waivers of the initial licensing fee for eligible low income and military family licensure applicants.

Proposed rule 11 CSR 13 is available for review and comment.

The Board encourages all interested persons to review the proposed rulemaking and provide comments on the proposed changes. All comments must be received by 4:30 pm on July 19, 2019, and should be submitted to:

Mark A. Spangler, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103

Charleston, West Virginia 25311
Mark.A.Spangier@wy.gov

*



State of West Virginia *Board of Medicine*

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VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 25, 2019

VIA ELECTRONIC MAIL ONLY

Sudha Reddy
suvreddy@yahoo.com

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 1B

Dear Dr. Reddy:

Thank you for taking the time to review the Board's proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*.

The Legislative Committee of the Board met on Tuesday, July 23, 2019, to review and consider all of the comments that were received. Discussion occurred, and the Board approved some modifications to the proposed rule in response to the comments it received. Enclosed please find a summary of the comments received, which addresses each suggested modification proposed in the comments, and the Board's responses.

The agency-approved version of 11 CSR 1B will be filed with the West Virginia Secretary of State's Office this week and will be available for review on their website at <https://apps.sos.wv.gov/adlaw/csr/>.

Thank you again for your participation in the rulemaking process.

Sincerely,

Mark A. Spangler

MAS/jcf
Enclosure

West Virginia Board of Medicine

101 Dee Drive, Suite 103

Charleston, West Virginia 25311

June 28, 2019

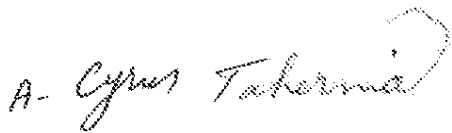
License Number 13187

Re: Proposed 11 CSR 1 B

Dear Board of Medicine of West Virginia: I support 11 CSR 1 B which is compatible with Senate Bill 668 with respect to physician assistant practice except for one of provision for requirement of CME for physician assistant and/or physician who are retired, it does need to have continued medical education to renew their medical license

This is completely true that this individual cannot practice in State of West Virginia and in my view is superfluous.

Respectfully Submitted,

A handwritten signature in cursive script that reads "A. Cyrus Tahernia". The signature is written in dark ink and is positioned above the printed name.

Cyrus Tahernia, MD, Emeritus



State of West Virginia *Board of Medicine*

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VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 25, 2019

VIA ELECTRONIC MAIL ONLY

A. Cyrus Tahernia, MD Emeritus
actahernia@gmail.com

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 1B

Dear Dr. Tahernia:

Thank you for taking the time to review and comment on the Board's proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*.

The Legislative Committee of the Board met on Tuesday, July 23, 2019, to review and consider all of the comments that were received. Discussion occurred, and the Board approved some modifications to the proposed rule in response to the comments it received. Enclosed please find a summary of the comments received, which addresses each suggested modification proposed in the comments, and the Board's responses.

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Thank you again for your participation in the rulemaking process and for your comments.

Sincerely,

Mark A. Spangler

MAS/jcf
Enclosure

Frame, Jamie C

Subject: FW: [External] Physician Assistants Rule Public Comments
Attachments: Physician Assistants Rule Public Commnets.docx

From: Brandon Hatfield <bhatfield@wvha.org>
Sent: Friday, July 12, 2019 1:07 PM
To: Spangler, Mark A <Mark.A.Spangler@wv.gov>
Cc: Tony Gregory <tggregory@wvha.org>
Subject: [External] Physician Assistants Rule Public Comments

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are expecting the content. — WV Office of Technology

Mark-

Please find attached the WVHA's public comments relating to 11CSR1B. If you have any questions, please let me know. I hope you're having a great summer!

Thanks



Brandon Hatfield

General Counsel
bhatfield@wvha.org

West Virginia Hospital Association

100 Association Drive
Charleston, West Virginia 25311
Office (304) 353-9720



100 Association Drive
Charleston, WV 25311-1571
Phone (304)344-9744
www.wvha.org

July 11, 2019

Mark A. Spangler, Executive Director
101 Dee Drive, Suite 103
Charleston, WV 25311

Dear Mr. Spangler:

Re: LEGISLATIVE RULE 11CSR1B, LICENSURE, DISCIPLINARY AND COMPLAINT PROCEDURES, CONTINUING EDUCATION, PHYSICIAN ASSISTANTS

On behalf of the West Virginia Hospital Association and its 63 member hospitals and health systems, we respectfully submit this letter to provide public comments in response to the above referenced **Legislative Rule 11CSR1B, Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants**.

§11-1B-2. Definitions.

2.1. "Hospital"- The definition of "hospital" has been amended in this rule to add additional restrictions not found in the authorizing legislation. Additionally, the changes to this definition conflict with the definition of "hospital" in the authorizing legislation. We would recommend removing the additional language proposed to be added to the definition of "hospital" to avoid confusion and to maintain consistency between the rule and the statute.

If you have any questions or concerns, please contact me at (304) 353-9720.

Sincerely,

Brandon Hatfield
General Counsel



State of West Virginia *Board of Medicine*

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Brandon Hatfield, Esq.
West Virginia Hospital Association
bhatfield@wvha.org

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 1B

Dear Mr. Hatfield:

Thank you for taking the time to review and comment on the Board's proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*.

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Thank you again for your participation in the rulemaking process and for your comments.

Sincerely,

Mark A. Spangler

MAS/jcf
Enclosure

Frame, Jamie C

From: Spangler, Mark A
Sent: Tuesday, July 16, 2019 12:31 PM
To: Frame, Jamie C
Subject: Fwd: [External] WVBOM comment period - proposed amendments to 11 CSR 1B and Proposed rule 11 CSR 13
Attachments: WVBOM.docx; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Culver, Gary R" <gculver@marshall.edu>
Date: July 16, 2019 at 12:18:27 PM EDT
To: "Mark A. Spangler@wv.gov" <Mark.A.Spangler@wv.gov>
Cc: "eightwrights@gmail.com" <eightwrights@gmail.com>
Subject: [External] WVBOM comment period - proposed amendments to 11 CSR 1B and Proposed rule 11 CSR 13

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Mark A. Spangler, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311
Mark.A.Spangler@wv.gov

Dear Mr. Spangler,

I have reviewed the WVBOM proposed amendments to 11 CSR 1B and proposed rule 11 CSR 13. I appreciate the efforts made by you and the rest of the WVBOM to help modernize PA practice in our state and for you part in the successful passage of this year's Bill 668. I was, however, disappointed that the bill didn't encompass all physician assistants who fall under institutional hospital credentialing, but rather only those who work inpatient. I work at Marshall Health and it should be noted that our entire organization is subject to the Cabell Huntington Hospital credentialing process so naturally I thought we would be included in this initial phase of modernization. To me it just made sense.

That said, this is a significant step in forward and I hope it will be followed in the years to come by legislation that will realize and embrace the wisdom of removing the necessity for individual practice agreements. The physician assistant profession has matured and has a 50 + year successful history and proven track record. Combine that with all the changes in health care administration and practice, the time has come to allow PA's to be individually licensed (like all other professions) and enabled to practice according to their education and training (in collaboration with physicians) without direct physician tethering.

Thank you, and the WVBOM, for your consideration of my thoughts and concerns. Please do not hesitate to contact me if you have any questions.

Sincerely,

Gary Reed Culver, PA-C, MMS
Marshall Health
1600 Medical Center Drive
Huntington WV, 25571
(304) 691-1152 - work
(304) 634-8503 - cell
Grculverx@marshall.edu

Mark A. Spangler, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311
Mark.A.Spangler@wv.gov

Dear Mr. Spangler,

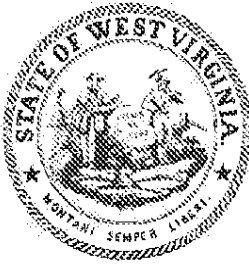
I appreciate the efforts made by you and the rest of the WVBOM to help modernize PA practice in our state and the successful passage of this year's Bill 668. I was however, disappointed that the bill didn't encompass all physician assistants who fall under institutional hospital credentialing, but only those who work inpatient. I work at Marshall Health and it should be noted that our entire organization is subject to the Cabell Huntington Hospital credentialing process so naturally I thought we would be included in this initial phase of modernization. To me it just made sense.

That said, this is a significant step in forward and I hope it will be followed in the years to come by legislation that will realize and embrace the wisdom of removing the necessity for individual practice agreements. The physician assistant profession has certainly matured and given the 50 + year successful history, proven track record, combined with the changes in modern health care dynamics, the time has come to allow PA's to be individually licensed (like all other professions) and enabled to practice according to their education and training (in collaboration with physicians) without direct physician tethering.

Thank you, and the WVBOM, for your consideration of my thoughts and concerns. Please do not hesitate to contact me if you have any questions.

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State of West Virginia *Board of Medicine*

KISHORE K. CHALLA, MD, FACC
PRESIDENT

CATHERINE C. SLEMP, MD, MPH
SECRETARY

101 Dee Drive, Suite 103
Charleston, WV 25311
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www.wvbom.wv.gov

ASHISH P. SHETH, MD
VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 25, 2019

VIA ELECTRONIC MAIL ONLY

Gary Reed Culver, PA-C, MMS
gculver@marshall.edu

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 1B

Dear Mr. Culver:

Thank you for taking the time to review and comment on the Board's proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*.

The Legislative Committee of the Board met on Tuesday, July 23, 2019, to review and consider all of the comments that were received. Discussion occurred, and the Board approved some modifications to the proposed rule in response to the comments it received. Enclosed please find a summary of the comments received, which addresses each suggested modification proposed in the comments, and the Board's responses.

The agency-approved version of 11 CSR 1B will be filed with the West Virginia Secretary of State's Office this week and will be available for review on their website at <https://apps.sos.wv.gov/adlaw/csr/>.

Thank you again for your participation in the rulemaking process and for your comments.

Sincerely,

Mark A. Spangler

MAS/jcf
Enclosure

Frame, Jamie C

Subject: FW: [External] Public comment period

From: Boles, Ginger <gboles@marshall.edu>
Sent: Wednesday, July 17, 2019 3:18 PM
To: Spangler, Mark A <Mark.A.Spangler@wv.gov>
Subject: [External] Public comment period

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are expecting the content. -- WV Office of Technology

Dr. Mr. Spangler,

This email is in response to the notice of Public Comment Period on 11CSR1B – Title 11- Legislative Rule –West Virginia Board of Medicine – Series 1B- Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants

I have concerns as to the new definition that was added and can be found on page 4, 2.1.gg. "Prescriptive authority" means the authority of a physician assistant to prescribe, order, administer or dispense prescription drugs. The word order in this context could create confusion for physician assistants who are working in hospitals where treatment and medication orders are written. I do not think it is the intent of these rules, based on recent statutory changes, to make prescriptions and orders one and the same. There has always been a clear distinction that a prescription for a medication is for outpatient delivery, while an order for a medication is for inpatient delivery. The DEA confirms this in the following statement which can be found on their website; a prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription). As such, medication orders within an institutional setting for immediate delivery have never been nor should they be regulated by a PA formulary intended for prescriptive authority.

I appreciate that your Board, the medical community and their professional associations recognized the changing health care delivery environment and supported legislation that will allow physician assistants to be utilized under an active practice notification. In keeping with the intent of this legislation, I would respectfully ask that the proposed rules be changed, as the Board of Medicine deems necessary to make sure that all the sections dealing with order or orders does not create confusion or unintentionally limit the well-established practice of physician assistants writing orders within a hospital based upon the protocols, guidelines, and best practices of the institution.

Respectfully,

Ginger Boles, MS PA-C
Founding Physician Assistant Program Director
Joan C. Edwards School of Medicine
Marshall University
1600 Medical Center Dr, Office 3403
Huntington, WV 25701
304-691-1979 (phone)
gboles@marshall.edu

****Marshall University Physician Assistant Program has applied for Accreditation - Provisional from the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA). Marshall University anticipates matriculating its first class in January of 2021, pending achieving Accreditation - Provisional status at the June of 2020 ARC-PA meeting. Accreditation - Provisional is an accreditation status granted when the plans and resource allocation, if fully implemented as planned, of a proposed program that has not yet enrolled students appear to demonstrate the program's ability to meet the ARC-PA Standards or when a program holding accreditation-provisional status appears to demonstrate continued progress in complying with the Standards as it prepares for the graduation of the first class (cohort) of students. The Marshall University Physician Assistant Program will not commence in the event provisional accreditation is not received.**



State of West Virginia *Board of Medicine*

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VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 25, 2019

VIA ELECTRONIC MAIL ONLY

Ginger Boles, MS PA-C
bolesg@marshall.edu

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 1B

Dear Ms. Boles:

Thank you for taking the time to review and comment on the Board's proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*.

The Legislative Committee of the Board met on Tuesday, July 23, 2019, to review and consider all of the comments that were received. Discussion occurred, and the Board approved some modifications to the proposed rule in response to the comments it received. Enclosed please find a summary of the comments received, which addresses each suggested modification proposed in the comments, and the Board's responses.

The agency-approved version of 11 CSR 1B will be filed with the West Virginia Secretary of State's Office this week and will be available for review on their website at <https://apps.sos.wv.gov/adlaw/csr/>.

Thank you again for your participation in the rulemaking process and for your comments.

Sincerely,

Mark A. Spangler

MAS/jcf
Enclosure


Frame, Jamie C

From: Spangler, Mark A
Sent: Saturday, July 20, 2019 12:41 AM
To: Frame, Jamie C
Subject: Fwd: [External] Comments on Title-Series 11-01B Relevant to the Enactment of SB 668
Attachments: AAPA WVAPA Final Comments Re Rules for SB 668 7.19.19.pdf; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: Stephanie Radix <sradix@aapa.org>
Date: July 19, 2019 at 2:37:57 PM EDT
To: "Mark A. Spangler@wv.gov" <Mark.A.Spangler@wv.gov>
Subject: [External] Comments on Title-Series 11-01B Relevant to the Enactment of SB 668

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Dear Mr. Spangler,

I hope this email finds you well and having a good summer.

Attached to this email you'll find comments from AAPA and the WV Association of PAs (WVAPA) relevant to proposed rule Title-Series 11-01B, regarding the implementation of SB 668.

Best,
Stephanie

Stephanie Radix, JD
Sr. Director, Constituent Organization Outreach and Advocacy
AAPA
P 571-319-4355
E sradix@aapa.org



July 19, 2019

Mark A. Spangler, Executive Director
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, WV 25311

**RE: Proposed Regulations to Implement Statutory Changes in SB 668 Regarding PAs
(Physician Assistants) Collaborating in Hospitals with Physicians**

Dear Mr. Spangler,

The American Academy of PAs (AAPA), is the national professional organization for PAs (physician assistants). In this capacity, AAPA represents more than 131,000 PAs across all medical and surgical specialties in all 50 states, the District of Columbia, U.S. territories, and the uniformed services.

AAPA appreciates the opportunity to submit comments on behalf of both AAPA and the West Virginia Association of PAs (WVAPA) on the proposed regulations relevant to a PA's ability to collaborate with physicians in hospitals pursuant to the enactment of Senate Bill 668 during the 2019 regular session of the West Virginia legislature. Upon review of the proposed regulations, we have some issues regarding the proposed language. Specifically, AAPA is concerned that the proposed regulations directly conflict with the intent and perceived goals of the underlying statute. These concerns and other relevant matters are discussed in detail below.

The revised law streamlines practice procedures, by eliminating the requirement for PAs who collaborate with physicians in hospitals to execute a practice agreement with a collaborating physician that must be filed with and approved by the appropriate licensing board (the West Virginia Board of Medicine or West Virginia Board of Osteopathic Medicine respectively). Under the new law, PAs in hospital settings are now required to file a practice notification in order to provide patient care.

In addition to eliminating board-approved practice agreements for hospital-based PAs who collaborate with physicians, other improvements to the regulation of the profession were achieved through the amended law regarding:

- **Scope of practice**—the scope of practice for PAs providing care in hospitals is determined at the practice level as approved by the hospital.
- **Ratios**—current ratio restrictions (5 full-time PAs: 1 physician) will no longer apply to PA-physician teams in hospitals; these determinations will be made at the practice level in accordance with facility policy.

- **Physician responsibility**—physicians are no longer responsible for the care a PA provides when the physician has no involvement with the patient. All PAs in West Virginia, regardless of practice setting, are individually responsible for the care they provide.

Based on these clear changes that are supported by the legislature's intent, we feel the proposed language fails to align with the goal and intent of SB 668 in addressing the following:

PRACTICE NOTIFICATIONS

The law provides that a physician may collaborate with PAs in a hospital as approved by the hospital.¹ In addition, the law defines a "practice notification" to mean "a written notice to the appropriate licensing board that a PA will practice in collaboration with one or more physicians in a hospital in the state of West Virginia."² (The proposed regulations seek to adopt the identical definition).³ The law also states that, "a license issued to a PA by the appropriate licensing board shall authorize the PA to perform medical acts: (1) pursuant to a practice notification [...]; (2) appropriate to the education, training, and experience of the physician assistant; (3) customary to the practice of the collaborating physician; and (4) consistent with the laws of this state and rules of the boards."⁴

AAPA is concerned that portions of the proposed regulations require practice notifications to include specific medical acts which form a component of a PA's scope of practice. For example, the section of proposed rules titled, Scope of Practice, under §11-1B-9, subsections 9.5. and 9.5.b. provide:

9.5. A physician assistant may provide an authorized signature, certification, stamp, verification, affidavit or endorsement on documents within the scope of his or her practice, including, but not limited to the following:

[...]

9.5.b. Medical certifications for death certificates if the physician assistant has received training on the completion thereof and this medical act is identified in the physician assistant's practice agreement or practice notification.

In addition, §11-1B-14 (14.4, 14.4.c) titled, Practice Notifications, states:

14.4. A practice notification shall include:

[...]

¹ W. VA. CODE ANN. §30-3E-9(f) (LEXISNEXIS 2019).

² W. VA. CODE ANN. §30-3E-1(16) (LEXISNEXIS 2019).

³ W. VA. CODE R. §11-1B-2 (2.1.dd) (LEXISNEXIS 2019).

⁴ W. VA. CODE ANN. §30-3E-12(a) (LEXISNEXIS 2019).

14.4.c Notification of whether or not the physician assistant is authorized to sign death certificates on behalf of the hospital;

Given the law and its legislative intent, the authority to perform specific acts like medical certifications for death certificates and the authority to sign death certificates on behalf of the hospital should not be required for inclusion in a practice notification. To that end, §11-1B-14 (14.4.c) should be eliminated entirely and §11-1B-9(9.5.b) should be amended. Potential amended language could read as follows:

§11-1B-9 Scope of Practice.

[...]

9.5.a. A physician assistant may provide an authorized signature, certification, stamp, verification, affidavit or endorsement on documents within the scope of his or her practice, including, but not limited to the following:

[...]

9.5.b Medical certifications for death certificates if the physician assistant has received training on the completion thereof and this medical act is identified in the physician assistant's practice agreement or practice notification appropriately delegated to the physician assistant in a hospital setting to perform.

PRESCRIPTIVE AUTHORITY PURSUANT TO A PRACTICE NOTIFICATION

The summary of proposed changes in the rule states, "The proposed amendments do not alter [...] prescriptive authority for physician assistants." The proposed regulations also provide that prescriptive authority for PAs practicing pursuant to an active practice notification must do so as set forth in section 15 of the rule. However, as proposed, only PAs who have prescriptive authority pursuant to a practice agreement under § 11-1B-12 (12.15) have authorization to accept professional samples and may apply to be registered as a controlled substance dispensing practitioner. The rules should make it clear that PAs practicing in hospitals have parallel authority under section 15.

GENERAL MATTERS

§11-1B-2. Definitions

As proposed, §11-1B-2, subsection 2.1.xt. needs to be amended to fix a grammatical error. The phrase physician assistant needs to continue to be pluralized. In the proposed rule the "s" has been stricken but should be re-inserted. The proposal currently reads as follows:

"Licensure" means the process of application to the Board, and the Board's consideration and approval of individuals ~~by the Board~~ to practice as a

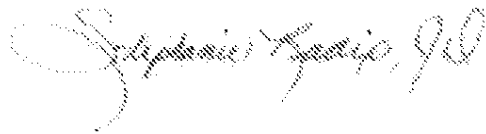
~~physician assistants to a medical doctor and/or podiatric physician in collaboration with physicians, and the process of application and consideration for this authorization.~~

We believe it should be amended to read:

~~"Licensure" means the process of application to the Board, and the Board's consideration and approval of individuals by the Board to practice as a physician assistant to a medical doctor and/or podiatric physician in collaboration with physicians, and the process of application and consideration for this authorization.~~

Thank you for the opportunity to provide feedback on the proposed rules to implement SB 668. AAPA welcomes further discussion with the Board regarding our comments and recommendations. For any questions you may have regarding our comments please do not hesitate to contact me directly.

Sincerely,



Stephanie Radix, JD
Senior Director, State Advocacy and Outreach
sradix@aapa.org

cc: Travis Randolph, PA-C
President, WVAPA

Janice Shipe-Spotloe, PA-C, DFAAPA, CPAAPA
Past President, WVAPA



State of West Virginia *Board of Medicine*

KISHORE K. CHALLA, MD, FACC
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ASHISH P. SHETH, MD
VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 25, 2019

VIA ELECTRONIC MAIL ONLY

Stephanie Radix, JD
American Academy of Physician Assistants /
West Virginia Association of Physician Assistants
radix@aspa.org

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 1B

Dear Ms. Radix:

Thank you for taking the time to review and comment on the Board's proposed amendments to 11 CSR 1B, *Licensure, Disciplinary and Complaint Procedures, Continuing Education, Physician Assistants*.

The Legislative Committee of the Board met on Tuesday, July 23, 2019, to review and consider all of the comments that were received. Discussion occurred, and the Board approved some modifications to the proposed rule in response to the comments it received. Enclosed please find a summary of the comments received, which addresses each suggested modification proposed in the comments, and the Board's responses.

The agency-approved version of 11 CSR 1B will be filed with the West Virginia Secretary of State's Office this week and will be available for review on their website at <https://apps.sos.wv.gov/adlaw/csr/>.

Thank you again for your participation in the rulemaking process and for your comments.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Spangler".

Mark A. Spangler

MAS/jcf
Enclosure